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Et al.

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Cluster Randomized Trials and Statistical Power

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The cluster-randomized trial (CRT) is a common study design in public health research. In situations where dividing a group of individuals into treatment and controls is unethical or impossible, a CRT design maintains the strengths of a randomized study design. By comparing the outcomes of small populations (clusters), we can observe the impacts of interventions on the community as a whole. Public health researchers around the world have utilized CRTs to measure the effect of, for example, de-worming medication on school attendance, financial incentives on doctor absenteeism, and providing chlorine to waterholes.

The CRT can be a potent tool, however it is not without flaws. As with an individually randomized trial, it often requires a large sample size (i.e. many clusters) to achieve adequate levels of power for its results. Existing formulas to estimate power for a study design frequently rely on simplifications of the study design. Addressing common challenges that researchers face when calculating power – such as variability in cluster sizes and uncertainty in between-cluster variability – we illustrate how these features affect power and demonstrate the utility of a simulation-based power calculation methodology.

Using R and the clusterPower package, we conducted a simulation study to quantify how variability in cluster size can influence the statistical power of a study. From this study, we provide concrete guidelines that can assist in the design phase of future CRTs, whether for testing a vaccine in Thailand or legislation in America.